

Exhibit K

7 DO NOT DISCLOSE - SUBJECT TO FURTHER
8 CONFIDENTIALITY REVIEW

9 July 28, 2017
0 Washington, D.C.

1 Videotaped Deposition of:

2 RONALD A. THISTED,

3 Called for oral examination by counsel for
4 Plaintiff, pursuant to notice, at the offices
5 of Nelson Mullins, 101 Constitution Avenue, NW,
6 9th Floor, Washington, D.C. beginning at 8:55
7 a.m., before Teague Gibson, a Notary Public.

. 8

.9

* * * *

21

2

3

34

35

1 A Accept by accident, they might turn out
2 for other reasons to have recorded something that
3 turns out to be a confounder, but.

4 Q So if after the study is completed they
5 determine that there are one or more confounders
6 that were either unmeasured or were previously
7 unknown and now are identified as potential
8 confounders, wouldn't you turn to external sources
9 of data to gain information about those potential
10 confounders?

11 MR. BUSMAN: Object to the form.

12 A Some sources of information might tell you
13 how often those confounders occurred in a particular
14 population, others may have been the basis for
15 identifying it as something that affects the
16 outcomes and those might play into an analysis of
17 the extent to which those -- that confounder could
18 have affected the outcomes of the PRESERVE study,
19 but they wouldn't tell you the answer to the
20 question that PRESERVE study is intended to answer.

21 Q Do you agree that MAUDE is part of FDA
22 adverse events surveillance system?

23 A Yes.

24 Q As we discussed, drug reports go into a
25 separate database, but it's similar in the sense

1 they're both collecting spontaneous adverse events,
2 right?

3 MR. BUSMAN: Object to the form.

4 A They're collecting -- both MAUDE and the
5 FDA adverse event reporting system are recruiting
6 both spontaneous adverse event reports -- yeah, they
7 both collect spontaneous adverse event reports.

8 Q And do you agree that the FDA advises
9 medical device manufacturers to calculate reporting
10 rates, that is adverse event -- reported adverse
11 events against sales or some other source or
12 exposure information?

13 MR. BUSMAN: Object to the form.

14 A I'm aware that FDA has guidance that
15 suggests as a signal detection measure that one
16 calculate crude rates of adverse events against a
17 measure of exposure. In the context of drugs one,
18 again, crude measure of exposure is number of
19 prescriptions sold. And the reason that's at least
20 a plausible measure of exposure is that the longer a
21 person is on a particular drug, the more
22 prescriptions they fill. So the more prescriptions
23 reflects extent of exposure. And someone who's on a
24 drug for a short time will have fewer prescriptions
25 than individuals on for a long time.

1 Same thing can't be -- isn't true for things
2 like devices where number of sales is the number of
3 implants but has no relationship to exposure, other
4 than initial exposure. But in the context of drugs,
5 FDA does suggest looking at crude estimates of
6 adverse event rates.

7 Q And, in fact, they say that comparison of
8 reporting rates and their temporal trends can be
9 valuable, particularly across similar products or
10 across different product classes?

11 MR. BUSMAN: Are you reading from -- I'm
12 just -- quick question. Is this a quote that
13 you're reading from or is it a question?

14 Q I'm just asking a question.

15 A I believe that's consistent with the 2005
16 guidance document on pharmacovigilance, but it can
17 be helpful in identifying possible trends but that
18 same document goes on to describe the limitations of
19 such things. It says, in particular, that because
20 reporting to change over time because there can be
21 differences in reporting rates for different drugs
22 or different products, that they can't be relied
23 upon for making causal comparisons between two
24 products.

25 Q The 2005 guidance document, is that the